II

111TH CONGRESS
1ST SESSION

S. 613

To prohibit the use of Federal funds to approve certain biologics license applications by the Food and Drug Administration.

IN THE SENATE OF THE UNITED STATES

MARCH 17, 2009

Mr. BROWNBACK introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To prohibit the use of Federal funds to approve certain biologics license applications by the Food and Drug Administration.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PROHIBITION ON USE OF FEDERAL FUNDS TO APPROVAL CERTAIN BIOLOGICS LICENSE APPLICATIONS.

Notwithstanding any other provision of law, no funds provided by any Appropriations Act enacted before the date of enactment of this Act that remain unobligated as of such date of enactment shall be used by the Food and Drug Administration to process a biologics license applica-

tion under section 351 of the Public Health Service Act (42 U.S.C. 262) for any such product for which—

(1) information submitted in such application, or any other information available to the Secretary of Health and Human Services, shows that the biologic product is, bears, or contains a listed select agent or toxin within the meaning of part 331 of title 7, Code of Federal Regulations, part 121 of title 9, Code of Federal Regulations, and part 73 of title 42, Code of Federal Regulations; and

(2) the entity filing such application has, during the 2-year period before the date of submission of such application to the Secretary—

(A) marketed, sold, or distributed that product in the Islamic Republic of Iran;

(B) provided select agents or toxins to institutions in the Islamic Republic of Iran, including to the Pasteur Institute in Tehran and Tehran University;

(C) submitted patient safety or efficacy data produced through experiments or trials that would violate the laws of the United States governing the proper handling of select agents or toxins; or

(D) been the subject of an investigation by the Office of Foreign Assets Control of the Department of Treasury, the Bureau of Industry and Security of the Department of Commerce, or the Department of Justice for potential violations of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note).

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